DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–19–19BN]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Emergency Cruise Ship Outbreak Investigations (CSOIs)* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on November 27, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Emergency Cruise Ship Outbreak Investigations (CSOIs)—Existing Collection in Use without an OMB Control Number—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Established in 1975 as a cooperative activity with the cruise ship industry, the Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program (VSP) develops and implements comprehensive sanitation programs to minimize the risk of gastrointestinal diseases, by coordinating and conducting operational inspections, ongoing surveillance of gastrointestinal illness, and outbreak investigations on vessels.

Under the authority of the Public Health Service Act (42 U.S.C. Sections 264 and 269), the VSP is requesting a three-year approval for a new generic clearance information collection request (ICR). This ICR will provide the quick turn-around necessary to conduct emergency cruise ship outbreak investigations (CSOIs) in response to acute gastroenteritis (AGE) outbreaks. CSOIs are used to determine the causative agents and their sources, modes of transmission, or risk factors. The VSP's jurisdiction includes passenger vessels carrying 13 or more people sailing from foreign ports and within 15 days of arriving at a U.S. port.

VSP uses its syndromic surveillance system called the Maritime Illness and Death Reporting System (MIDRS) (approved under ''Foreign Quarantine Regulations'' [OMB Control No. 0920–0134, expiration date 05/31/2019]) to collect aggregate data about the number of people onboard ships in VSP's jurisdiction who are experiencing AGE symptoms. When the levels of illness meet VSP's alert threshold (*i.e.,* at least 2% in either the passenger or crew populations), a special report is made to VSP via MIDRS and remote environmental health and epidemiologic assistance is provided. VSP considers an outbreak to be ≥3% of reportable AGE cases in either guest or crew populations. When assistance is needed due to AGE outbreaks on cruise ships, this often requires VSP to deploy a response team to meet the ship in port within 24 hours of reaching the outbreak threshold, and in some cases deploying the response team to board the ship before its U.S. arrival and sail back to the U.S. port of disembarkation to conduct a more detailed and comprehensive epidemiologic and environmental health evaluation of the outbreak.

Causative agent, sources of exposure, modes of transmission, and risk factors can be ascertained by gathering the following types of information from both the affected and (seemingly) unaffected populations:

- Demographic information,
- Pre-embarkation travel information,
- Symptoms, including type, onset, duration,
- Contact with people who were sick or their body fluids,
- Participation in ship and shore activities,
- Locations of eating and drinking, and
- Foods and beverages consumed both on the ship and on shore.

Rapid and flexible data collection is imperative given the mobile environment, the remaining duration of the voyage left for investigation, and the loss to follow-up if delays allow passengers to disembark and leave the ship, including those returning to locations outside of the U.S.

This new generic clearance will cover investigations that meet all of the following criteria:

- The investigation is urgent in nature (*i.e.,* timely data are needed to inform rapid public health action to prevent or reduce morbidity or mortality).
- The investigation is characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors.
- One or more CDC staff (including trainees and fellows) will be deployed to the field.
- Most CSOIs involve two to five days of data collection; data collection is completed in 30 days or less.

This new generic clearance excludes each of the following:

- Investigations related to non-urgent outbreaks or events.
- Investigations conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (*e.g.,* to contribute to generalizable knowledge).
- Investigations with data collection expected for greater than 30 days.

The VSP estimates 10 CSOIs annually in response to cruise ship AGE

outbreaks. The estimated number of respondents is 2,500 per CSOI, for a total of 25,000 respondents per year. The average time burden is 15 minutes for each respondent. Therefore, the total estimated annual burden in hours is 6,250. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Cruise Ship Passengers or Crew	Questionnaire	24,750	1	15/60
	Interview	250	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–1143; Docket No. CDC–2019–0009]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled US Zika Pregnancy registry, is to seek Paperwork Reduction Act (PRA) clearance to monitor the frequency and types of adverse birth outcomes for women with laboratory evidence of Zika virus infection during pregnancy and their infants and to strengthen the public health response to the Zika virus disease outbreak.

DATES: CDC must receive written comments on or before May 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0009 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

US Zika Pregnancy Registry (OMB Control No. 0920–1143, Expiration 11/30/2019)—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. As of March 16, 2016, local transmission has been identified in at least 32 countries or territories in the Americas. Further spread to other countries in the region is likely. Local vector-borne transmission of Zika virus has not been documented in the 50 U.S. states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands, and American Samoa. However, Zika virus infections have been reported in travelers returning to the United States from areas with active Zika virus transmission. Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for Zika virus acquisition. With the ongoing outbreak in the Americas, the number of Zika virus disease cases among travelers returning to the United States likely will